4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-D-0226]

Guidance for Industry, Third Parties and Food and Drug Administration Staff; Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled "Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program." This guidance document is intended to provide information on the implementation of the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amends the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This guidance document describes how FDA's Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER) are implementing this provision of the law. The Pilot Program will be effective June 5, 2012.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled "Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program" to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993-0002 or Office of Communication, Outreach and

Development (HFM-40), 1401 Rockville Pike, suite 200N, Rockville, MD 20852. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301-847-8149. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the guidance.

Submit electronic comments on the guidance to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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I. Background

This guidance document is intended to provide information on the implementation of section 228 of FDAAA (Public Law 110-85), which amends section 704(g)(7) of the FD&C Act (21 U.S.C. 374(g)(7)). Under this guidance document, a device manufacturer whose establishment has been audited under one of the regulatory systems implemented by the Global Harmonization Task Force (GHTF) founding members[1] using International Organization for Standardization (ISO) 13485:2003 "Medical devices – Quality management systems – Requirements for regulatory purposes" and ISO 13485:2003 Technical Corrigendum 1:2009 "Medical devices – Quality management systems – Requirements for regulatory purposes," (ISO 13485:2003) or a national adoption of this standard, e.g., EUROPEAN STANDARD EN ISO 13485 July 2003 + AC August 2009, "Medical devices - Quality management systems – Requirements for regulatory purposes" (ISO 13485:2003 + Cor 1:2009) (EN ISO 13485:2003/AC:2009), National Standard of Canada CAN/CSA-ISO 13485:03 (ISO 13485:2003) "Medical devices — Quality management systems — Requirements for regulatory purposes" (Reaffirmed 2008) (CAN/CAS ISO 13485 13485:2003)), may voluntarily submit the resulting audit report to FDA. If, based on that report, FDA determines that there is minimal probability--in light of the relationship between the quality system deficiencies observed and the particular device and manufacturing processes involved--that the establishment will produce nonconforming and/or defective finished devices,[2] then FDA intends to use the audit results as

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[1] The GHTF founding members auditing systems include: The Canadian Medical Devices Conformity Assessment System; the European Union Notified Body Accreditation System; the Therapeutics Goods Administration of Australia Inspectorate; and the Japanese Ministry of Health, Labour and Welfare System for Medical Devices and In-Vitro Diagnostics.

[2] See February 2, 2011, Compliance Program (CP) 7382.845 Inspection of Medical Device Manufacturers Part V http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072753.htm.

part of its risk assessment to determine whether that establishment can be removed from FDA's routine work plan for 1 year. The voluntarily submitted ISO 13485:2003 "Medical devices – Quality management systems – Requirements for regulatory purposes" and ISO 13485:2003 Technical Corrigendum 1:2009 "Medical devices – Quality management systems – Requirements for regulatory purposes," (ISO 13485:2003) audit report provides FDA a degree of assurance of compliance with basic and fundamental quality management system requirements for medical devices.

The medical device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program outlined in the guidance is another way in which FDA may leverage audits performed by other GHTF regulators and their accredited third parties in order to assist FDA in setting risk-based inspectional priorities.

The draft guidance document entitled, "Medical Device ISO 13485:2003 Voluntary Audit Report Submission Program" was published for comment in the Federal Register of May 20, 2010 (75 FR 28257). Comments on the collection information were due July 19, 2010, and comments on the draft guidance document were due by August 18, 2010.

FDA received comments and suggestions to pilot this program for a period of time; an evaluation will follow to allow both FDA and industry to work out potential issues, obstacles, and resource allocations. FDA agrees and has decided to pilot this ISO 13485 Voluntary Audit Report Submission Program for a period of 2 years effective June 5, 2012. FDA will then evaluate the program and report on the findings and any issues or suggested changes.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's current thinking on "Medical Device

ISO 13485:2003 Voluntary Audit Report Submission Pilot Program." It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by using the Internet. A search capability for all CDRH guidance documents is available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm. Guidance documents are also available at http://www.regulations.gov or from the CBER Internet site at http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm. To receive "Medical Device ISO 13485:2003 Voluntary Audit Report Submission Pilot Program" you may either send an email request to dsmica@fda.hhs.gov to receive an electronic copy of the document or send a fax request to 301-847-8149 to receive a hard copy. Please use the document number 1746 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520). The collection(s) of information in this guidance was approved under OMB control number 0910-0700. This final guidance also refers to currently approved collections of information found in FDA regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 820 are currently approved under OMB control number 0910-0073 and the collections of information for

the Inspection by Accredited Persons Program are currently approved under OMB control number 0910-0569.

V. Comments

Interested persons may submit to the Division of Dockets Management (see ADDRESSES), either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 13, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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